

Dr. Mann Pharma - Berlin

Formulation A

HERSTELLBERICHT FÜR ENTWICKLUNGSSCHARGEN

- Augengele -

| | | | | |
|------------------|-----------------|-------------|---------------|-----------|
| Präparat: | Ch-Bez.: GLG | Ansatzgröße | Herstelldatum | TEIL I |
| Dauermarken: R/L | | 5009 | | |

Bemerkungen (z.B. Grund der Herstellung):

Hersteller: to
Prüfer (Teil 1): to

HERSTELLUNG:

BESONDERHEITEN BEI DER HERSTELLUNG: Bei der Einwirkung von Dexamethason-10-phosphat wurde das Saatgut nicht berücksichtigt.

Stabilitätsprüfung von : Dexamann visc.
Chargennummer

Präp.Nr. 190

(10)

Chargengröße : 500 g
Behältnis : 5 g-Polyfoil-Kanületube, Innenbeschichtung: KOPE
Herstellungsort : Dr. Mann Pharma, Berlin
Herstelltdatum :
Erstuntersuchung :
Einfälgungsdatum :
Prüfdatum : Monate

05/94 3
09/94 7
02/95 12
08/95 18

Formulation A
pH 6,3 - 7,3

| Prüfung auf | Spezifi-kation | Lager-zeit in Mon. | Lagerungsbedingungen | | | |
|--|------------------------|--------------------|----------------------|----------|----------|----------|
| | | | 5°C | 21°C/45% | 26°C/60% | 31°C/70% |
| Gehalt in % Dexamethason-dihydrogen-phosphat | 90 - 105 | 0 | - | 96,2 | - | - |
| | | 3 | 96,8 | 95,7 | 96,2 | 96,5 |
| | | 7 | - | 95,8 | 96,7 | 92,5 |
| | | 12 | - | 95,1 | 91,7 | 89,2 |
| Gehalt in % Cetrimid | 90 - 105 | 18 | - | 86,3 | 86,0 | 83,9 |
| | | 0 | - | 95,9 | - | - |
| | | 3 | - | 101,5 | 101,6 | 99,0 |
| | | 7 | - | 98,0 | 97,7 | 97,6 |
| Dexamethason in % | max 10 % | 12 | - | 100,2 | 99,3 | 99,3 |
| | | 18 | - | - | - | - |
| | | 0 | - | n.n. | - | - |
| | | 3 | 0,7 | 1,4 | 1,6 | 1,8 |
| Transmission in % (bei 425 nm) | > 85 % | 7 | - | 2,4 | 2,9 | 3,1 |
| | | 12 | - | 5,6 | 3,5 | 4,0 |
| | | 18 | - | 10,7 | 11,2 | 12,9 |
| | | 0 | - | 91,8 | - | - |
| pH-Wert | 6,3 - 7,3 | 3 | 95,2 | 95,3 | 94,6 | 95,6 |
| | | 7 | - | - | - | - |
| | | 12 | - | 93,1 | 93,6 | 93,9 |
| | | 18 | - | 94,9 | 94,3 | - |
| Osmolalität (mosm/kg) | 285 - 335 | 0 | - | 304 | 298 | 301 |
| | | 3 | - | 300 | 300 | 303 |
| | | 7 | - | 301 | 300 | 303 |
| | | 12 | - | 328 | 299 | 303 |
| Leitfähigkeit (µS/cm) | 7 - 12 | 0 | - | 8,7 | - | - |
| | | 3 | 9,9 | 10,1 | 10,2 | 10,0 |
| | | 7 | - | - | - | - |
| | | 12 | - | - | - | - |
| Brechungsindex (n _D) | 1,339 - 1,341 | 0 | - | 1,3408 | - | - |
| | | 3 | 1,3407 | 1,3406 | 1,3405 | 1,3404 |
| | | 7 | - | 1,3407 | 1,3406 | 1,3406 |
| | | 12 | - | - | - | - |
| Viskosität (mPa·s) | 2000 - 3000 | 0 | - | 2846 | - | - |
| | | 3 | 2622 | 2642 | 2652 | 2734 |
| | | 7 | - | 2550 | 2799 | 2724 |
| | | 12 | - | 2911 | 2875 | - |
| Aussehen | klar (DAB 10/Ph. Eur.) | 18 | - | 2918 | 2857 | - |
| | | 0 | - | - | - | - |
| | | 3 | - | - | - | - |
| | | 7 | - | - | - | - |
| Farbe | B 9 (DAB 10/Ph. Eur.) | 12 | - | - | - | - |
| | | 18 | - | - | - | - |
| | | 0 | - | B 9 | B 9 | B 9 |
| | | 3 | - | B 9 | B 9 | B 9 |
| Mikrobiolog. Qualität | steril | 7 | - | B 9 | B 9 | B 9 |
| | | 12 | - | B 9 | B 9 | B 9 |
| | | 18 | - | B 9 | B 9 | B 9 |
| | | 0 | - | steril | - | - |

n.n. = nicht nachweisbar
- = nicht untersucht

HERSTELLBERICHT FÜR ENTWICKLUNGSSCHARGEN

- Augengele -

Präparat:

Dexamethason Gel

Ch.-Bez.:

Ansatzgröße

1Kg

Herstelldatum

TEIL

1

Bemerkungen (z. B. Grund der Herstellung):

Hersteller: FD

Prüfer (Teil 1): DH 15

Prüfdatum:

| Lfd. Nr. | WE-Nr. | Bezeichnung | Einwaage (g) | Gehalt nach Analyse mg/g | der Deklaration (%) |
|---|----------|---|-----------------|-----------------------------|------------------------|
| 1 | 086 0036 | Carbopol 990 | 3,00 | | |
| 2 | 045 0268 | Dexamethason - 21-dihydrogen sulfat * <small>phosphat gek. 21.6.2003</small> | 1.407 | | 102,8 |
| 3 | 056 0360 | Cetrimid | 0,100 | | 99,7% |
| 4 | 016 0055 | Na-edetat | 0,100 | | |
| 5 | 076 0322 | Sorbitol | 49,00 | | |
| 6 | 076 0214 | Natri. Fest | 1,50 | | |
| 7 | / | dest. Wasser | 1 | | |
| * H ₂ O-Gehalt der Substanz beachten = 11,05 / 1.945,193 | | | | | |

Stability test: Dexamethason Gel
 Batch number: [REDACTED]
 Batch size: 1 kg
 Container: 5 g Polyfoil tubes
 Place of manufacture: Dr. Mann Pharma, Berlin
 Date of manufacture: [REDACTED]
 Date of storage: [REDACTED]
 Test date months
 10/96 0
 02/97 3
 05/97 6
 08/97 9
 11/97 12
 05/98 18

Prod. no.: [REDACTED]

Formulation B
pH 7.6 - 8.0

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| Test for | Specification (release) | Months | Storage conditions | | |
|--|-------------------------|--------|--------------------|------------|------------|
| | | | 21 °C/45 % | 25 °C/60 % | 30 °C/70 % |
| Content [%] Dexamethasone sodium phosphate | 95 - 105 | 0 | 102.0 | | |
| | | 3 | 99.0 | 99.8 | 100.1 |
| | | 6 | 99.6 | 101.6 | 101.1 |
| | | 9 | 102.3 | 101.7 | 101.6 |
| | | 12 | 99.7 | 98.3 | 97.5 |
| | | 18 | 101.3 | 100.9 | 99.1 |
| Decomposition [%] Dexamethasone | n.m.t. 3 | 0 | 0.2 | | |
| | | 3 | 0.2 | 0.2 | 0.2 |
| | | 6 | 0.4 | 0.5 | 0.5 |
| | | 9 | 0.5 | 0.5 | 0.6 |
| | | 12 | 0.5 | 0.6 | 0.7 |
| | | 18 | 0.7 | 0.7 | 0.8 |
| Content [%] Cetrimide | 90 - 110 | 0 | 99.7 | | |
| | | 3 | 99.3 | 100.3 | 99.6 |
| | | 6 | 98.3 | 99.0 | 99.0 |
| | | 9 | 100.5 | 99.0 | 100.0 |
| | | 12 | 100.2 | 99.2 | 99.4 |
| | | 18 | 99.5 | 100.6 | 101.4 |
| Transmission [%] | n.i.t. 85 | 0 | 88.4 | | |
| | | 3 | 89.6 | 89.7 | 87.0 |
| | | 6 | 88.8 | 88.9 | 89.0 |
| | | 9 | 86.6 | 89.3 | 89.2 |
| | | 12 | 89.3 | 88.6 | 89.5 |
| | | 18 | 87.0 | 86.9 | 87.5 |
| pH value | 7.6 - 8.0 | 0 | 7.7 | | |
| | | 3 | 8.0 | 7.9 | 7.9 |
| | | 6 | 7.7 | 7.7 | 7.7 |
| | | 9 | 7.7 | 7.7 | 7.6 |
| | | 12 | 7.7 | 7.7 | 7.7 |
| | | 18 | 7.8 | 7.8 | 7.7 |
| Osmolality [mosmol/kg] | 290 - 320 | 0 | 305 | | |
| | | 3 | 303 | 304 | 304 |
| | | 6 | 304 | 305 | 306 |
| | | 9 | 312 | 307 | 308 |
| | | 12 | 308 | 307 | 307 |
| | | 18 | 305 | 306 | 306 |
| Viscosity [mPa·s] | 2400 - 3400 | 0 | 3075 | | |
| | | 3 | 2802 | 3451 | 3308 |
| | | 6 | 3502 | 3158 | 3403 |
| | | 9 | 2877 | 3178 | 3209 |
| | | 12 | 3022 | 3175 | 3132 |
| | | 18 | 3691 | 3804 | 3428 |

Stability test:

Dexamethas n Gel

Prod. no.: (4)

Batch number:

[REDACTED]

Batch size:

1 kg

Contain r.

5 g Polyfoil tubes

Place of manufacture:

Dr. Mann Pharma, Berlin

Date of manufacture:

[REDACTED]

Date of storage:

months

Test date

| | |
|-------|----|
| 10/96 | 0 |
| 02/97 | 3 |
| 05/97 | 6 |
| 08/97 | 9 |
| 11/97 | 12 |
| 05/98 | 18 |

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| Test for | Specification (release) | Months | Storage conditions | | |
|--------------------------------------|-------------------------------------|--------|--------------------|------------|------------|
| | | | 21 °C/45 % | 25 °C/60 % | 30 °C/70 % |
| Colour | B 9 | 0 | B 9 | | |
| | | 3 | B 9 | B 9 | B 9 |
| | | 6 | B 9 | B 9 | B 9 |
| | | 9 | B 9 | B 9 | B 9 |
| | | 12 | B 9 | B 9 | B 9 |
| | | 18 | B 9 | B 9 | B 9 |
| Clarity and degree of opalescence | n.m.t standard of opalescence IV | 0 | n.m.t IV | | |
| | | 3 | n.m.t IV | n.m.t IV | n.m.t IV |
| | | 6 | n.m.t IV | n.m.t IV | n.m.t IV |
| | | 9 | n.m.t IV | n.m.t IV | n.m.t IV |
| | | 12 | n.m.t IV | n.m.t IV | n.m.t IV |
| | | 18 | n.m.t IV | n.m.t IV | n.m.t IV |
| Sterility | sterile | 0 | sterile | | |